IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

CORDIS CORPORATION, *Plaintiff*, v. MEDTRONIC VASCULAR, INC., BOSTON SCIENTIFIC CORPORATION, and SCIMED LIFE SYSTEMS, INC., *Defendants*.	)	C.A. No. 97-550-SLR
MEDTRONIC VASCULAR, INC., *Plaintiff*, v. CORDIS CORPORATION, et al., *Defendants*.	)	C.A. No. 97-700-SLR

CORDIS' COMBINED ANSWERING BRIEF IN OPPOSITION TO AVE'S MOTION FOR JMOL ON INFRINGEMENT OF THE PALMAZ '762 AND SCHATZ '984 PATENTS AND ITS MOTION FOR A NEW TRIAL

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PRELIMINARY STATEMENT

AVE's motions for judgment as a matter of law and for a new trial are based largely on an argument that this Court has already explicitly considered and rejected: the argument that the Federal Circuit has established that there is only one proper way, as a matter of law, to measure the thickness of the wall surface of a stent. As this Court has already determined, however, the Federal Circuit did ***not*** "hold[] that one of ordinary skill would only measure thickness a certain way." D.I. 1337 (March 1, 2005 Memorandum Order) at 5. Therefore, it was for the jury to decide how one of ordinary skill in the art would measure "thickness" in this case, id., and it was also for the jury to decide whether AVE's MicroStent II, GFX, and GFX II stents as properly measured meet the "substantially uniform thickness" limitation.

Like the jury at the first trial in this action, the jury here found that AVE's stents meet the "substantially uniform thickness" limitation. (D.I. 1337.) Its verdict is supported by overwhelming evidence that one of ordinary skill in the art would measure "thickness" by measuring the cross-sectional diameter of the wire-like material constituting the stent walls, and that the wire forming AVE's stent walls is almost perfectly uniform in diameter.[1] This Court should once again reject AVE's argument that there is only one proper way to measure the thickness of a stent's wall surface, and deny AVE's motion for judgment as a matter of law.

Moreover, the exclusion at trial of limited and irrelevant evidence concerning AVE's stents' performance and AVE's own patents was correct and did not prejudice AVE. Arguments by Cordis' counsel, to which AVE now objects as "inflammatory" and "extraneous"

[1] The term "diameter" is used in this brief to describe the thickness at the center of both round and ellipto-rectangular struts.

(AVE Br. (D.I. 1398) at 2), were a fair summary of evidence in the record and were perfectly appropriate. The Court should therefore deny AVE's motion for a new trial.

STATEMENT OF FACTS

As this Court stated numerous times during the recent course of this litigation, the March 2005 trial was a limited retrial after the Federal Circuit found certain portions of the Court's claim construction to be in error.

All of the asserted claims in this action are directed at a tubular member with a wall surface having a "substantially uniform thickness." When this case was first tried, the Court had construed the claim term "substantially uniform thickness" such that "[v]ariances [in wall thickness] of as little as 0.001 [inch] [fell] outside the scope of 'substantially uniform.'" D.I. 790 at 2. The Federal Circuit rejected that construction as "unduly narrow," Cordis Corp. v. Medtronic AVE Inc., 339 F.3d 1352, 1360 (Fed. Cir. 2003), holding that "the walls must be… largely or approximately uniform," id. at 1361, and that "a wall that varies in thickness by as much as 100% cannot be said to be of 'substantially uniform thickness' either literally or by equivalents," id. at 1362.

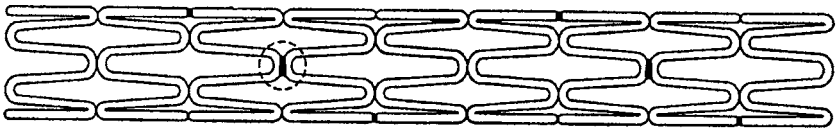
On remand, this Court reconstrued "substantially uniform thickness" to eliminate the 0.001 inch upper bound on variations in wall thickness. (D.I. 1251 at 1-2, n.1.) This Court also determined that AVE was entitled to re-try infringement of the "substantially uniform thickness" limitation and to try the obviousness of the asserted claims under the new claim construction.

The Court's final construction of "substantially uniform thickness," as given to the jury at the March trial, was that (D.I. 1357 (Jury Charge) at 23):

> The wall of a tubular member must be of largely or approximately uniform thickness. A wall that varies in thickness by as much as 100% cannot be said to be of substantially uniform thickness.

The Court did not instruct the jury that "thickness" was to be measured in a particular way, having previously held that measuring thickness is a matter of claim application and that "[t]he appropriate test for measuring the thickness of the wall surface at a strut's crowns is a question of fact for the jury." D.I. 1337 (3/1/05 Mem. Order) at 5.

The structure of AVE's stents was undisputed at trial. Both parties agreed that AVE's stents, as described by the Federal Circuit, are formed by "bending wire rings into sinusoidal shapes and then connecting the bent rings together, as [in the AVE engineering drawing that is] shown below," Cordis Corp., 339 F.3d at 1356:



As AVE's expert testified, each of the wire rings is made from "round" wire. (Trial Tr. at 1007:6-10 (AVE witness Allen)). AVE's witnesses characterized each bent ring as consisting of "straight sections" called "struts" and "rounded sections" called "crowns" (e.g., id. at 1002:23-1003:2 (Allen)), and further described the crowns as being "rounded and tapered" (id. at 1006:8).

The parties' single infringement dispute was how to apply the "substantially uniform thickness" limitation to AVE's "bent-wire" stents. Cordis offered evidence showing that one of ordinary skill in the art would apply that limitation by measuring the diameter of the cross-section of the wire constituting the stent wall, both at the "strut" and at the "crown," and comparing those measurements to see if they varied. AVE did not (and could not) dispute this for the struts, which constitute 98 percent of the stent. However, it argued that thickness at the tip of the crown should be measured differently and that "[b]ecause of the tapered crown, the

thickness of the Medtronic AVE stent wall will vary by more than a hundred percent." (Tr. at 179:5-7 (AVE Opening Argument).) As did the jury at the 2000 trial, this jury found Cordis' substantial evidence more persuasive and rendered a verdict that all three of the accused stents meet the "substantially uniform thickness" limitation of the asserted patent claims. (D.I. 1358 (Jury Verdict)). The jury also rendered a verdict that the asserted claims were not invalid. (Id.)

ARGUMENT

I. THE COURT SHOULD UPHOLD THE JURY'S VERDICT THAT AVE'S STENTS INFRINGE THE ASSERTED CLAIMS

A party seeking judgment as a matter of law following a jury trial must show that the jury could not have reasonably reached its verdict based on the evidence in the record (D.I. 1337 (3/1/05 Mem. Order) at 1):

> To prevail on a renewed motion for judgment as a matter of law following a jury trial under Federal Rule of Civil Procedure 50(b), the moving party "'must show that the jury's findings, presumed or express, are not supported by substantial evidence or, if they were, that the legal conclusions implied [by] the jury's verdict cannot in law be supported by those findings.'" Pannu v. Iolab Corp., 155 F. 3d 1344, 1348 (Fed. Cir. 1998) (quoting Perkin-Elmer Corp. v. Computervision Corp., 732 F. 2d 888, 893 (Fed. Cir. 1984)). "'Substantial' evidence is such relevant evidence from the record taken as a whole as might be acceptable by a reasonable mind as adequate to support the finding under review." Perkin-Elmer Corp., 732 F. 2d at 893.

In deciding AVE's motion for judgment as a matter of law, the Court must "view[] the evidence in the light most favorable to the [verdict winner] and giv[e] it the advantage of every fair and reasonable inference ….." Gagliardo v. Connaught Labs., Inc., 311 F.3d 565, 568 (3d Cir. 2002). Furthermore "[t]he [C]ourt may not determine the credibility of the witnesses, or substitute its resolution of conflicting evidence for that of the jury." Id. (citing GNB Battery Technologies, Inc. v. Exide Corp., 876 F. Supp. 582, 597 (D. Del. 1995)).

To prevail on its motion for judgment as a matter of law that its stents do not infringe the "substantially uniform thickness" limitations of the asserted claims, AVE must therefore show that when viewed in the light most favorable to Cordis, the trial "record is critically deficient of that minimum quantity of evidence from which [the] jury might reasonably [have] afford[ed] relief." Trabal v. Wells Fargo Armored Serv. Corp., 269 F.3d 243, 249 (3d Cir. 2001) (internal quotation omitted). AVE has not come close to such a showing.

A. Cordis Offered Overwhelming Evidence that AVE's Stents Meet the Substantially Uniform Thickness Limitation

Cordis' evidence showing that AVE's stents have walls of "substantially uniform thickness" far surpassed "that minimum quantity of evidence from which [the] jury might reasonably [have] afford[ed] relief." Trabal, 269 F.3d at 249. As the record shows, AVE did not and could not dispute the critical fact that the wire-like material that makes up its stent has a uniform diameter, and that when measured Cordis' way, its stents have walls of precisely uniform thickness. Thus, AVE's counsel told the jury in his opening argument (Tr. 180:20-24):

> There's no question that the ring from which the stent is made has a substantially uniform diameter. Again, nothing's perfect because of manufacturing tolerances, but that is a substantially uniform diameter.

Moreover, AVE conceded that the wall thickness in the strut sections and half the crown sections of AVE's stents, which constitute 98 percent of the stent, is perfectly uniform. The real dispute was limited to the remaining 2 percent of the stent – less than half of the crown section. Cordis showed that when AVE measured the thickness of the crowns in the ordinary course of business and reported those measurements to the FDA, it measured them the same way it measured the struts, and reported the thickness as being identically uniform.

1. Cordis' Evidence Showed that One of Ordinary Skill In the Art Would Determine "Substantially Uniform Thickness" By Measuring the Diameter of the Material Constituting the Wall

Cordis offered both substantial expert testimony and AVE's own internal engineering documents to show that a person of ordinary skill in the art would determine whether a bent-wire stent has walls of "substantially uniform thickness" by measuring the cross-sectional diameter of the wire constituting the walls at various points along the strut and crowns.

Cordis' expert, Dr. Collins, testified that one of ordinary skill would measure the stent wall's "thickness" by taking the cross-sectional diameter in exactly the same way at the strut and at the crown (Tr. at 513:7-17, 514:1-10):

> A. In measuring the thickness, the question is: What are you measuring? You're measuring the thickness of the strut, and that the strut is the structural element. So you want to measure the thickness of the cross-section of the structural element.
>
> …
>
> Q. And how would you take the thickness of the crown region?
>
> A. I would do the crown region…exactly the same way, you would take a cut through the structural element.

Dr. Collins further testified that one of ordinary skill would determine uniformity in thickness by measuring "multiple thicknesses in the strut region and multiple thicknesses in the crown region" and comparing them. (Tr. at 512:6-9.)

As Dr. Collins made clear, the shape of the cross-section (*e.g.*, round or ellipto-rectangular) does not affect the wall's thickness (or uniformity of thickness) under this method of measurement (Tr. at 515:16-22):

> Q. Does the shape of the cross-section matter in your infringement analysis?
>
> A. No. The shape of the cross-section doesn't effect [sic] the thickness, the thickness of the cross-section.

Dr. Collins then testified that AVE's internal engineering documents show that AVE engineers measure the thickness of AVE's stent walls using precisely the same method (Tr. 529:1-534:6; see also PX 7648 (AVE measurement protocol)):

> Q. Could you explain what's shown in the AVE documents [PX 7648], please?
>
> A. Sure. What's shown here is that the point number two is the thickness of the strut, so here is two, and what it's saying to do is look at the cross-section of the strut, just the same way that we did right there and measure the thickness.
>
> …
>
> Q. So during the regular course of business, AVE measures the cross-section of the strut just like you did?
>
> A. Exactly.
>
> …
>
> Q. How does AVE measure the thickness of the crown sections?
>
> A. They measure the thickness of the crown sections by measuring the thickness of the cross-section of the structural elements.
>
> Q. Is that consistent with the way an engineer would?
>
> A. Absolutely, yes.

AVE's written standards call for determining uniformity of thickness the same way Dr. Collins explained, by comparing the cross-sectional thickness at various points along the strut and crown. (Tr. at 530:11-531:19 (Dr. Collins explaining that AVE standards call for two measurements at the crown and two at the strut, and that "you take all those measurements and you look at the variations of the measurements to see if it was uniform or not uniform").)

AVE engineers used the method described by Cordis' expert in measuring the thickness of its stent walls and reported those measurements to the FDA. (See PX 41 and PX 2372.) Indeed, as Dr. Collins further testified, AVE even noted in its report to the FDA that the cross-sectional thickness dimension "is equivalent to the wall thickness of a slotted tube stent. …

So they're saying that dimension is the same as the wall thickness for a Palmaz type stent." (Tr. at 539:19-540:7.)

Cordis also presented undisputed evidence that when "substantially uniform thickness" is analyzed by determining whether there are variations in the cross-sectional diameter of the material constituting the stent wall, AVE's stents have precisely uniform thickness. Cordis offered documents and testimony showing that the struts and crowns of each of AVE's three stents have "very uniform" cross-sectional diameters (Tr. 537:3, 539:17-18), with standard variations of only one or two ten thousandths of an inch across the entire stent. (Tr. at 535:17-536:3 and PX 7577 (GFX standard thickness is .0049 inches with variation of .00013 inches); Tr. 537:10-21 and PX 2613 (GFX II standard thickness is .00532 with variation of .000178 inches); Tr. 540:13-15 and PX 2372 (MicroStent II standard thickness is .0085 inches with variation of .0002 inches); see also PX 42, 151, 3585, 49, and 2375 (AVE engineering drawings showing cross-section thickness and manufacturing tolerances)). These miniscule variances in thickness as reported in AVE's own internal measurements reflect AVE's "very tight [manufacturing] tolerances." (Tr. at 528:12-17.)

On cross-examination, AVE's engineer Jeffrey Allen confirmed the testimony of Cordis' witnesses that AVE reported to the FDA a uniform thickness at both the strut and the crown of its stents (Tr. 1077:4-21):

> Q. …The average measurement [reported to the FDA in PX 7577] is exactly the same as the average measurement for the crown thickness, 4.9 thousandths of an inch?
>
> A. Correct. That's what I said. …
>
> Q. What Mr. Birdsall reports as strut thickness, that's what he reports as crown thickness, same measurement?
>
> A. Yes.
>
> Q. Same standard deviation?

A. Yes.

Q. …[A]nd in fact, AVE reported these results to the FDA; isn't that correct?

A. Yes, we did.

Mr. Allen also agreed that the material constituting the stent walls has the "same [rounded] configuration everywhere" along the stent – what AVE describes in its promotional materials as a "smooth edgeless design." (Tr. at 1068:22-24.)

The testimony from both parties' witnesses, and AVE's engineering documents and FDA submissions, greatly exceeds the level of relevant evidence that "might be acceptable by a reasonable mind as adequate to support the finding" of infringement in this case. Perkin-Elmer Corp., 732 F. 2d at 893. Therefore, the Court should find that judgment as a matter of law in AVE's favor is unwarranted.

2. AVE Failed to Show That Its Stents Vary In Thickness By At Least 100%

AVE's stents are formed from round-wire hoops that have uniform thickness. Although the diameter of the wire remains uniform throughout the entire stent ring after the hoop is bent to form the ring, AVE attempted to convince the jury that the thickness of the curved portions of the ring (the crowns) should be analyzed differently from the thickness of the straight portions (the struts). As this Court noted, AVE's noninfringement defense "[wa]sn't very different from what the Federal Circuit rejected in the first instance." (Tr. at 231:2-7.)

AVE argued that an engineer would measure uniformity of thickness by thinking of an "imaginary circle on the inside of the stent and an imaginary circle on the outside of the stent," and then "mov[ing] those imaginary circles the length of the stent…to see if the stent wall has a uniform thickness by whether or not those circles stay the same distance apart." (Tr. 177:12-13.) Its engineering expert, Dr. Wagoner, testified that an engineer would measure

thickness using the "imaginary circle" method described above. (Tr. at 1101:8-1102:13, 1104:17-20.) Dr. Wagoner also testified that using that method, AVE's stent walls vary in thickness by more than 100% because as the two imaginary circles approach each other at the very tip of the stent, where the wire curves to form the crown, there is a point where the distance between the circles is half of the diameter of the wire. (E.g., Tr. at 1110:22-1111:16; see also Section B2 and B3, infra).

Notably, AVE's own internal documents showed that its engineers did not measure wall thickness the way Dr. Wagoner advocated. (See PX 7648, PX 7577, PX 2613, PX 2372, PX 42, PX 151, PX 49, PX 2375 and Tr. 529:1-540:15 (Collins testimony).) Moreover, Dr. Wagoner agreed that even under AVE's theory, 98 percent of AVE's stent wall has uniform thickness (Tr. 1135:14-1136:10):

> Q. So 98 percent of the stent is of uniform thickness, but you think your last two percent or so is not uniform; is that your testimony?
>
> A. Yes. That's correct.
>
> …
>
> Q. The struts are straight, but they have a curved cross-section?
>
> A. They're rounded in the cross-section, yes.
>
> Q. But you agree that they have a uniform thickness; correct?
>
> A. The wall has a uniform thickness in that area, yes.
>
> Q. And most of the crown also has a uniform thickness; isn't that correct, sir?
>
> A. Yes, more than half of it has the uniform form [sic] thickness.

In addition, Dr. Wagoner agreed that if Cordis' method of measuring thickness "is the right way to measure for purposes of the '762 patent, then the AVE stents have a uniform wall thickness." (Tr. at 1185:20-24.) And in light of Cordis' overwhelming evidence that one of

ordinary skill would simply measure thickness in the same way across the entire stent by taking the diameter of the cross-section, instead of employing imaginary circles at the crown of the stent, it is hardly surprising that the jury once again found Cordis' evidence more persuasive.

Cordis' evidence that AVE's stents have uniform wall thickness far surpasses the standard for defeating judgment as a matter of law. See Perkin-Elmer Corp., 732 F. 2d at 893 (verdict winner need only show evidence that "taken as a whole…might be acceptable by a reasonable mind as adequate to support the finding"). Judgment as a matter of law in AVE's favor is therefore unwarranted.

B. The Walls of AVE's Stents Do Not Vary By 100% As A Matter of Law, Under Either Cordis' or AVE's Method of Measuring Wall Thickness

In its brief, AVE ignores this Court's March 1, 2005 Order rejecting its argument (D.I. 1337), and further ignores Cordis' substantial evidence concerning the wall thickness of AVE's stents. Instead, it doggedly maintains its position that the Federal Circuit mandated AVE's preferred way to measure "thickness." AVE's argument has three critical flaws: first, as this Court has already correctly held, the Federal Circuit did not hold that there is a single way to measure "wall thickness"; second, as described in the Federal Circuit opinion, the "Federal Circuit method" advocated by AVE is in fact consistent with, and not an alternative to, Cordis' method of measurement; and third, AVE's stent does not vary in thickness by 100% as a matter of law even under the so-called "Federal Circuit method."

1. The "Federal Circuit Method" is Actually a Method for Measuring Thickness in the Manner Cordis Advocates

Underlying AVE's entire JMOL motion is the premise – already rejected by this Court – that the Federal Circuit required a particular method of measuring wall thickness. AVE argues that the Federal Circuit separately construed the word "thickness" when it wrote that

"[t]he thickness of the [stent's] wall is equal to the diameter of each round strut, *i.e.*, the distance between the outer point that intersects the wall surface and the corresponding inner point that intersects a similar imaginary cylindrical surface on the inside of the tubular member." (D.I. 1397 (here after "AVE JMOL Br.") at 8.)

However, as this Court explained in its March 1, 2005 Order, ***"[t]he appropriate test for measuring the thickness of the wall surface*** at the crowns ***is a question of fact for the jury, not a matter of law determined by the Federal Circuit."*** (D.I. 1337 at 5-6 (emphasis added).) The Court further held that ***"the Federal Circuit's discussion with respect to measuring the thickness of a stent does not amount to a holding that one of ordinary skill would only measure thickness in a certain way,"*** and it concluded that ***"each party can present evidence with respect to how one of ordinary skill in the art would measure the thickness of the wall surface."*** Id. (emphasis added).

Indeed, the Federal Circuit did not have to construe the term "thickness," because there was no dispute over how to measure thickness on the record of the 2000 trial: "both AVE's and Cordis's experts agreed that ***persons of ordinary skill in the art equate thickness with diameter in the case of round struts.***" Cordis Corp., 339 F.3d at 1362 (emphasis added). Thus, the only question for the Federal Circuit was how to apply the claim limitation "substantially uniform thickness" to determine the uniformity of the cross-sectional diameter of the material constituting AVE's stent walls. The Federal Circuit's "concentric circles" method was an illustration of how to measure uniformity in thickness ***by measuring the diameter of the material*** (id. (emphasis added):

> ***The thickness of the wall is equal to the diameter of each round strut, i.e.***, the distance between the outer point that intersects the wall surface and the corresponding inner point that intersects a similar imaginary cylindrical surface on the inside of the tubular

> member. ***Thus, a stent with round struts can have a substantially uniform thickness as long as the round struts have substantially the same diameter.***

The "concentric circles" method is one way of applying the "substantially uniform thickness" limitation to AVE's stents in view of the agreement between both sides' experts that persons of ordinary skill in the art would measure thickness by measuring the cross-sectional diameter of the material constituting the stent walls. As the Federal Circuit's opinion makes clear, the "concentric circles" method is not, as AVE contends, an alternative to measuring the uniformity of the diameter.

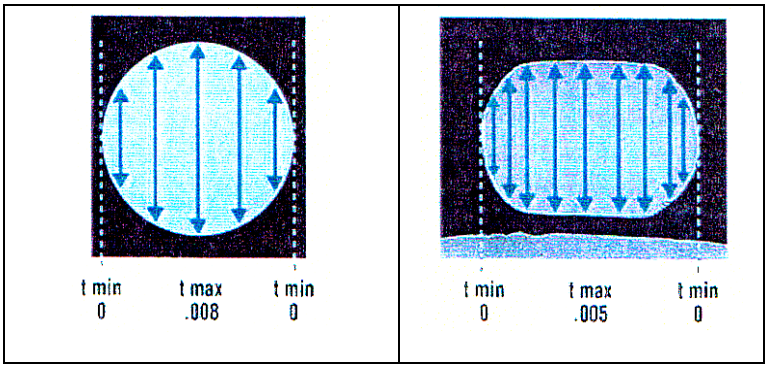
2. AVE's Stents Do Not Have a 100% Variation in Wall Thickness as a Matter of Law

Based on its misreading of the Federal Circuit's opinion, AVE further argues that "[w]hen the actual 'walls' of the AVE stents are measured in the manner the Federal Circuit described, the undisputed evidence established that there are variations in [wall] thickness of at least 100%." (AVE JMOL Br. at 15.) But AVE draws the wrong conclusions from the Federal Circuit opinion. As shown above, the Federal Circuit merely described one way to analyze the "wall thickness" of the stent, namely, the cross-sectional diameter of the material constituting the stent wall. And even AVE's engineering expert admitted that if cross-sectional diameter equals wall thickness, then AVE's stents have walls of substantially uniform thickness. (See Tr. at 1185:20-24.)

Moreover, the Federal Circuit itself has already rejected the proposition that AVE's stents have a 100% variation in thickness as a matter of law. On appeal after the first infringement verdict in this action, Cordis established that during the '762 reexamination it distinguished Ersek's non-uniform thickness by relying on the double thickness or 100% variation at Ersek's bridge points. In response, AVE argued that its "bent wire-like stents" lack a

"substantially uniform thickness" even under Cordis' approach because (in AVE's view) they vary in thickness by "at least 100%." (Ex. A hereto at 26, 44-45.)

As it did before the jury in March, AVE based its "100% variation" argument to the Federal Circuit on the fact that the cross-section of its stents' bent wire-like material is round (for the MicroStent II) or ellipto-rectangular (for the GFX), as shown in the following drawings from AVE's appeal brief (id. at 25 and 44):



AVE argued on appeal that "[a]s shown in Figure 1 [reproduced above], the maximum thickness ['t max'] is present only at the struts' center [i.e., the diameter], and the thickness tapers off to zero ('t min equals zero') towards the edge." (Ex. A hereto at 26.) AVE's position was that its stents "var[y] in thickness from a minimum of almost zero [at the rounded edge of the cross-section] to a maximum of either .008 [for the MicroStent II] or .005 inches [for the GFX] [at the diameter], a variation of at least 100%." Id. at 26; see also id. at 44-45, 52.

The Federal Circuit explicitly rejected AVE's argument that its stents varied in thickness by at least 100%:

> AVE contends that, under either party's construction, its stents have a variable thickness because they have a round or ellipto-rectangular cross-section and thus do not infringe because the cross-sectional thickness of its stent walls varies by more than 100%. ***We disagree ….***

Cordis Corp., 339 F.3d at 1362 (emphasis added). It further reasoned that if thickness is equated with diameter (which AVE's expert did not then dispute) (id.):

a stent with round struts can have a substantially uniform thickness as long as the round struts have substantially the same diameter.

In other words, the Federal Circuit found that "thickness" is the "diameter in the case of round struts," and that AVE's stents cannot vary by 100% solely by virtue of having a round cross-section. In arguing that the tips of the crowns should be treated differently from the rest of the stent when their configuration and thickness is the same, AVE's defense ran directly counter to the Federal Circuit's decision in this case. As the Court observed after hearing AVE's opening statement in the trial, AVE's entire noninfringement defense "[wa]sn't very different from what the Federal Circuit rejected in the first instance." (Tr. at 231:2-7.) The jury in the March trial must be presumed to have found that AVE's stents do not have a 100% variation in wall thickness, see McGinley v. Franklin Sports, Inc., 262 F.3d 1339, 1359 (Fed. Cir. 2001), and it could reasonably have done so by employing the same analysis as the Federal Circuit.

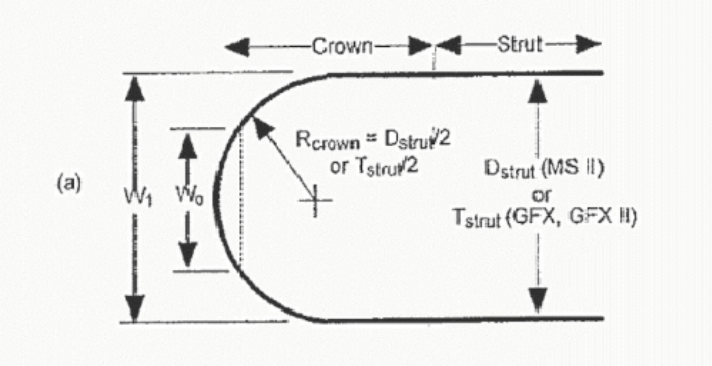
AVE argues (AVE JMOL Br. at 11) that Cordis' method of measurement would eliminate the "100% variation" element for all practical purposes. Not so. Under Cordis' (and the Federal Circuit's) method of measurement, a stent formed of uniformly round wire could have a double thickness if two pieces of the wire cross over each other at any point on the stent, exactly as Dr. Palmaz's early woven-wire embodiments did. Cordis' method of measurement does not make it impossible for a stent with walls formed of round wire to have "double thickness," and is entirely consistent with Cordis' disclaimer.

3. Cordis' Arguments Concerning the 100% Variation in Thickness Were Entirely Proper

In a variation on the same theme, AVE caricatures Cordis' argument as an assertion that "'you can't have' a stent with a 100% variation in wall thickness" (AVE JMOL Br. at 11), and that a 100% "deviation" in a stent's wall thickness is "mathematically impossible,"

(AVE JMOL Br. at 10). AVE misrepresents Cordis' argument. Contrary to AVE's assertions, Cordis did ***not*** argue that "'you can't have' a stent with 100% variation in wall thickness" – it merely disputed the method AVE's expert used to calculate a "100% variation" and cross-examined that expert to show that one of ordinary skill would have used a different method.

To illustrate the method Dr. Wagoner used to calculate 100% variation, Cordis' counsel showed him a demonstrative taken from his expert report, shown below:



Dr. Wagoner agreed that T_{strut}, D_{strut}, and W_1 all represent "the thickness of the strut." (Tr. 1136:19-23, 1166:21-24.) As Dr. Wagoner also testified, under his theory of calculating a 100% variation in thickness, "W_o is where -- …if you compare that cross-section with the – a general section in the middle of the segment, that's where the wall thickness varies by a hundred percent exactly." (Tr. at 1162:2-10.)

Cordis' counsel then asked Dr. Wagoner whether, if W_1 – the stent wall's thickness for the 98 percent of the stent – was the reference point for calculating variation instead of W_0, it was possible for AVE's stents to fall under the "100% variation" escape clause by having a wall thickness that deviated downward by 100%. AVE's expert readily agreed that a 100% negative deviation based on W_1, the wall's nominal thickness, was mathematically impossible (Tr. at 1167:13 – 1168:1 (emphasis added)):

> Q. …I'm asking that instead of starting from a slither as a reference point, you start from the thickness of the strut as your reference point and attempt to measure any deviation around the curve, you will agree with me that as a mathematical matter there cannot be a hundred percent negative deviation?
>
> A. Deviation, a hundred percent deviation?

Q. Yes.

A. That's a different question. ***I agree with that***.

AVE's expert also testified that "that's not the way [he] understand[s] variation." (Tr. at 1175:10-11.) But the jury was free to disbelieve AVE's evidence concerning the proper basis for calculating variation. There is no reason for the Court to presume that the jury reached a common-sense conclusion – namely, that the nominal thickness should be the basis for calculating variation, as opposed to the thickness of an arbitrary sliver at the end of the crown – because it was "confus[ed]" (AVE JMOL Br. at 10), or that the jury's conclusion is impermissible as a matter of law.

4. Cordis Did Not Ignore the Crowns of the AVE Stents

AVE's final argument, that "Cordis's infringement analysis ignores the crowns of the AVE stents" (AVE JMOL Br. at 15), is refuted by the record. Cordis' engineering expert, Dr. Collins, explicitly addressed both the struts and the crowns, testifying that he would measure the thickness of the crown region "in exactly the same way" as he would measure the thickness of the struts (Tr. at 514:1-10), and that to measure uniformity he would "measure multiple thicknesses in the strut region and multiple thicknesses in the crown region" (Tr. at 512:6-9).

Furthermore, Dr. Collins discussed AVE's internal measurement documents at length, testifying that AVE's regular business method, like his method, was to measure multiple thicknesses in the strut and crown regions. (Tr. at 530:11-531:19.) Explaining AVE's own documents to the jury, Dr. Collins testified that when AVE measured its stents using the above method and reported the results to the FDA, it reported a uniform thickness of 4.9 thousandths of an inch for the entire GFX stent; a uniform thickness of 5.32 thousandths of an inch for the entire GFX II stent; and a uniform thickness of 8.5 thousandths of an inch for the entire MicroStent II.

(Tr. at 529:18-540:15 (also noting manufacturing tolerances reported by AVE); see also PX 7648, PX 7577, PX 2613, PX 41, and PX 2372.)

Thus, far from ignoring the crown regions of AVE's stents, Cordis presented substantial evidence from which the jury could have found, and must be presumed to have found, McGinley, 262 F.3d at 1359, that both the crown and strut regions of AVE's stents meet the "substantially uniform thickness" limitation. Therefore, Cordis' argument – and AVE's expert's admission (Tr. 1135:14-1136:10) – that the variation in thickness as advocated by AVE "extends over only a limited portion of the length of the [stent's] wall" (AVE JMOL Br. at 16), is not a basis for granting AVE judgment as a matter of law.

II. THE COURT SHOULD NOT GRANT AVE A THIRD TRIAL

AVE no more deserves a new trial than it deserves judgment as a matter of law.

"[T]he district court's power to grant a new trial motion is limited to those circumstances 'where a miscarriage of justice would result if the verdict were to stand.'" Olefins Trading, Inc. v. Han Yang Chem. Corp., 9 F.3d 282, 289-90 (3d Cir. 1993) (quoting Fineman v. Armstrong World Indus., Inc., 980 F.2d 171, 211 (3d Cir. 1992)); see also Moore, Federal Practice & Procedure § 59.13[2][a] (as a general principle courts will not disturb a jury verdict in absence of extreme circumstances, such as manifest injustice or abuse of the jury's function). The purpose of limiting new trials to such extraordinary circumstances "is to ensure that the trial court does not supplant the jury verdict with its own interpretation of the facts." Id.

In determining whether a new trial is warranted based on an error, courts make a two-part inquiry, first determining "whether an error was in fact committed, and [then…] whether that error was so prejudicial that denial of a new trial would be inconsistent with substantial justice." Arthrocare Corp. v. Smith & Nephew, Inc., 310 F. Supp. 2d 638, 666 (D. Del. 2004). If the court determines that an error was made, such as in the admission or exclusion

of evidence, the court should not grant a new trial if it is "highly probable" that the error did not contribute to the judgment. McQueeney v. Wilmington Trust Co., 779 F. 2d 916, 923-28 (3d Cir. 1985); Fed. R. Civ. P. 61 ("The court at every stage…must disregard any error or defect in the proceeding which does not affect the substantial rights of the parties.").

To obtain a new trial based on misconduct of counsel, the moving party must establish that the conduct was not mere aggressive advocacy, and that the misconduct is prejudicial in the context of the entire trial record. Moore, Federal Practice & Procedure § 59.13[2][c][i][A]; Genzyme Corp. v. Atrium Med. Corp., 315 F. Supp. 2d 552, 584 (D. Del. 2004); Stambler v. RSA Sec., Inc., 2003 WL 22749855, at *7 (D. Del. Nov. 14, 2003) (attached hereto as Ex. B); Henry v. Hess Oil Virgin Islands Corp., 163 F.R.D. 237, 241-242 (D.V.I. 1995). The Third Circuit has recognized that attorneys are generally given "great latitude in their arguments," Waldorf v. Shuta, 142 F.3d 601, 628 (3d Cir. 1998) (denying new trial motion), and that "not all improper remarks will engender sufficient prejudice to mandate the granting of a new trial," Fineman, 980 F.2d at 207. Therefore, the test for determining whether to grant a new trial is whether the attorney made improper assertions and, if so, whether "the improper assertions have made it 'reasonably probable' that the verdict was influenced by prejudicial statements." Greate Bay Hotel & Casino v. Tose, 34 F.3d 1227, 1236 (3d Cir. 1994) (quotations and citations omitted); Fineman, 980 F.2d at 207; Henry, 163 F.R.D. at 242 n.3.

AVE cannot show that a new trial is warranted because it has not shown – and cannot show – that a "'miscarriage of justice would result if the verdict were to stand.'" Olefins, 9 F.3d at 289-90. To the contrary, two juries and the Federal Circuit have rejected all of AVE's noninfringement and invalidity theories to date, based on the substantial evidence offered by

Cordis showing that AVE's three accused stents infringe all five of the asserted patent claims, and that all five claims are valid and enforceable.

A. The Court Properly Allowed the Parties to Present Evidence and Argument Concerning the Proper Method of Measuring Thickness and Variations in Thickness

Three of AVE's alleged points of error relate to AVE's fundamentally incorrect assertion that under the Federal Circuit decision, the only permissible method of measuring thickness is the method advocated by AVE (see D.I. 1398 (hereafter "AVE Br." at 14)). However, as shown above, the Federal Circuit neither construed the term "thickness" nor held that there is a single permissible method of measuring variations in thickness (see supra Sections I(B)(1)-(2)). The parties were free to advocate their own theories of measurement at trial, and the Court properly prohibited the parties from claiming that their theories were endorsed by the Federal Circuit. Therefore, none of the points AVE raises warrant a new infringement trial.

1. Cordis' Arguments Concerning the "100% Variation" Element Were Proper

Cordis offered overwhelming evidence at trial, much of it undisputed, that persons of ordinary skill in the art would measure thickness by measuring the diameter of the wire forming the wall of AVE's stents, and that because AVE's stents are formed of wire with nearly perfectly uniform thickness, AVE's stents meet the "substantially uniform thickness" limitation. (See supra Section IA.)

Having failed to convince the jury that its stents' wall thicknesses "vary by as much as 100%," AVE now claims that Cordis' counsel misled the jury into ignoring the 100% variation requirement (AVE Br. at 8) by arguing that "you can't have a hundred percent deviation" (id.). However, as the record shows, the argument AVE finds so objectionable simply

called into question AVE's method of measuring variations in thickness, based on an admission by AVE's own engineering expert.

As Cordis attempted to show through cross-examination of AVE's engineering expert, one needs a reference point for determine whether a thickness "varies by as much as 100%." As described above (supra Section I(B)(3)), AVE advocated basing the 100% calculation on the "thickness" of a sliver of the tip of the stent, whereas Cordis advocated basing the 100% calculation on the nominal thickness of the stent, i.e., the cross-sectional diameter of the material constituting the stent. AVE's expert Dr. Wagoner agreed that if the proper basis for the 100% calculation is the diameter of the stent, it is not mathematically possible for the stent to have a wall thickness that deviates downward by 100%. (See Tr. at 1167:13 – 1168:1; supra Section I(B)(3)). This simple and undisputed mathematical proposition is the basis for the remarks that AVE characterizes as "grossly misleading" (AVE Br. at 10).

Far from misleading the jury, Cordis' counsel merely showed through cross-examination that if the proper way to apply the Court's claim construction to AVE's stents is to determine whether AVE's stent wall varies in thickness ***by 100% of the diameter***, then AVE's stents do not fall within the "100% variation" exclusion. Nothing in the claim construction establishes as a matter of law that the cross-sectional diameter is an improper basis for calculating percentage variation. The jury as fact-finder was therefore not required to believe AVE's evidence that the calculation should be based on something other than the diameter. Cordis' counsel's remarks, based on AVE's expert testimony, were perfectly proper. They were based on the testimony of AVE's expert and do not warrant a new trial. See Fineman, 980 F.2d at 207.

2. Cordis' Arguments Regarding "100% Variation" Were Consistent with the Federal Circuit Opinion and the '762 Patent's File History

Second, AVE argues that Cordis' method of calculating percentage variation based on diameter is "flatly inconsistent" with the Federal Circuit's opinion and the asserted patents' file history, because it "render[s] meaningless" the "100% variation" element of the Court's claim construction.

However, Cordis' position does no such thing. Cordis agrees that a bent-wire stent with a wall thickness ranging from the diameter to two times the diameter, thereby varying ***upward*** by 100% of the diameter, would not have a "substantially uniform thickness." (See supra Section I(B)(2).) Cordis' position is perfectly consistent with Cordis' statement to the Patent Office that the Ersek sleeve "does not have a substantially uniform wall thickness" because it "is twice as thick in some areas as in others." (AVE Br. at 12, quoting PX-13 at PWRAP 003079 SUB). As Cordis explained, the Ersek device, which is formed from expanded metal, has "bridge" portions where two metal "strands" come together, and the bridges are twice as thick as the strands. (See, e.g., Tr. at 779:10-24 (Dr. Buller testifying as to figure 5 of the Ersek patent); see also Tr. at 1392:11-17 (AVE expert Dr. Piehler agreeing that the "knuckle" or "bridge" portions of expanded metal "invariably" have "a dimension that is twice the dimension of the strand")).

Because Cordis' cross-examination and arguments concerning "100% variation" were perfectly consistent both with the asserted patents' file history and the Court's claim construction, the Court decided not to further instruct the jury concerning the "100% variation" element of its claim construction. The Court's decision was correct and cannot be the basis for granting AVE a new trial. See Arthrocare, 310 F. Supp. 2d at 671 (no need to consider prejudice if the court did not err).

3. The Court Correctly Precluded the Parties From Eliciting Testimony Concerning the Federal Circuit's Opinion

AVE's final argument concerning the "100% variation" element is based on the same misreading of the Federal Circuit's opinion that underlies its motion for judgment as a matter of law, namely that its "circle within a circle" infringement analysis is "mandatory" under the Federal Circuit's opinion. (AVE Br. at 14.) AVE argues that because Cordis was allowed to challenge its expert's testimony that an engineer of ordinary skill in the art would use the "imaginary circles" method of measurement, it should have been allowed to "point out to the jury that its methodology had been endorsed by the Federal Circuit." (AVE Br. at 14-15.)

As Cordis has shown, the Federal Circuit opinion does not mandate a particular infringement analysis. (See supra Section I(B)(1)-(2).) Instead, the portion of the Federal Circuit's opinion on which AVE relies is merely an illustration of how one might measure variations in the diameter of the material constituting the stent wall. (Id.) Moreover, even if the Federal Circuit had mandated a particular infringement analysis, the proper course of action for this Court would have been to so instruct the jury, not to allow AVE's engineers and cardiologists to testify about the Federal Circuit's opinion. See, e.g., United States v. Leo , 941 F.2d 181, 196 (3d Cir. 1991) ("it is not permissible for a witness to testify as to the governing law since it is the district court's duty to explain the law to the jury"). Because the Court's decision to exclude such testimony was correct, it cannot be the basis for granting a new trial. See Arthrocare, 310 F. Supp. 2d at 671.

B. The Court's Decision to Exclude Certain Evidence Concerning AVE's Stents and Patents Was Not Error and Did Not Affect a Substantial Right of AVE

Two of AVE's points of alleged error concern this Court's exclusion of some evidence relating to its stents and patents. However, the Court was correct to exclude this

irrelevant evidence. Furthermore, despite the Court's *in limine* rulings, AVE in fact presented lengthy testimony concerning the purported superiority of its stents, told the jury that it had stent-related patents, and alluded repeatedly to AVE's "proprietary" stent technology. Having done so, AVE cannot complain of the Court's evidentiary rulings. AVE's own conduct makes it "highly probable" that those rulings did not contribute to the judgment and defeats AVE's argument for a new trial. See McQueeney, 779 F.2d at 923-28.

1. AVE Was Not Prejudiced by the Exclusion of Certain Evidence Concerning the "Clinical Significance" of the AVE Stents' "Variably Thick Crowns"

As Cordis showed in its *in limine* motion on the subject (D.I. 1292 at Tab 9), evidence concerning the alleged clinical significance of AVE's "variably thick crowns" was irrelevant because an accused product that has every claim limitation cannot avoid infringement merely by improving on the claimed invention. See Atlas Powder Co. v. E.I. du Pont De Nemours & Co., 750 F.2d 1569, 1580 (Fed. Cir. 1984); see also Amstar Corp. v. Envirotech Corp., 730 F.2d 1476, 1482 (Fed. Cir. 1984) ("'[I]nfringement cannot be avoided by the mere fact that the accused device is more . . . efficient or performs additional functions.'" (citation omitted)). Such evidence was therefore properly excluded.

Furthermore, AVE is wrong when it states that the Court "prevented AVE from presenting some of the most crucial evidence… – namely, that the variations in thickness near the ends of the AVE stents are clinically significant." (AVE Br. at 16.) Despite the Court's decision granting Cordis' *in limine* motion to exclude such evidence in the context of infringement (D.I. 1337 (3/1/05 Mem. Order) at 8), AVE's infringement witnesses testified at every opportunity that its stents' so-called "tapered leading edges" were of clinical importance. For instance, AVE's first witness, an AVE engineer, testified that when AVE tried to laser-cut its stents instead of forming them from bent wire (Tr. at 1016:1-24 (Allen)):

> the stents don't perform the same way….[Y]ou don't end up with these nice rounded tapered crowns. And, you know, you can test the stents on the bench top, and you get similar information, similar data, but you actually take it to the clinic and take it to the animal and you try to track these things through these three dimensional tortuous vessels, and these vessels, they're not like a snakey road, they're more like those crazy roller coasters that you go on….[A]nd if you don't have these nice tapered round crowns, [the stents are] harder to push.

Mr. Allen further testified that the "tapered leading edge" is (Tr. at 1024:9-17):

> a critical design feature…for several reasons. One, I've talked about how they track and move through the vessels. They're also critical in terms of the stresses, and the strains that occur in that crown, both when we form the stent, and when the stent is being flexed, and loaded in the coronary arteries.

See also Tr. at 1036:16-1037:3 and PX 43 (Allen testimony that AVE marketing brochure "communicat[es]" the "significance of [the tapered crowns, which] is that it minimizes resistance in the vessel…and disruption of the vessel").

Like Mr. Allen, AVE's engineering expert testified at length that the "tapered end" of AVE's stents has clinical benefits (Tr. at 1126:1 – 1128:12):

> The clinical significance is clear as an engineer, I can see easily that this kind of…rounded tapered strut design would go through a tube, an artery much more readily than if it was not there.
>
> * * *
>
> Q. … Are the tapered ends of the AVE stents an important design feature in your opinion?
>
> A. They're very important. They are – they're critical to the design of this stent. … I undertook some independent study of early clinical trials to understand the importance of that, and I saw doctor after doctor who did the early trials that said that was a very important feature of retractability and getting in the body. To me, it's in fact – I mean, I've seen AVE's promotional documents where they talk about that as a very important feature. I've also seen Cordis' documents where they say it's a wonderfully deliverable stent related to that feature. … Just in the same way [that the ball point tip is critical to the ball point pen] these rounded struts,

> rounded crown areas are critically important to an AVE stent operation.

In short, AVE presented extensive evidence of the benefits of its rounded leading edge. Two AVE witnesses – Mr. Allen and Dr. Wagoner – testified at length on that subject. Further testimony would only have been cumulative, and its exclusion did not cause any prejudice to AVE.

2. AVE Was Not Prejudiced by the Exclusion of Certain Evidence Concerning Secondary Considerations

AVE also objects broadly to the exclusion of certain evidence, including evidence of the purported clinical superiority of AVE's stents, AVE's stent patents, and comparisons of AVE's stents to Cordis' stents, in light of argument and evidence that Dr. Palmaz's invention of the balloon-expandable coronary stent created today's coronary stent industry (AVE Br. at 24). AVE's theory is that by referencing Dr. Palmaz's status as a pioneer whose work underlies an entire field of research, and by accusing AVE of practicing Dr. Palmaz's invention, Cordis relied on the success of AVE's stents as a secondary consideration of nonobviousness, and also accused AVE of copying. (AVE Br. at 24.) However, Cordis did not "open the door" in the manner AVE suggests, and even so AVE offered significant evidence of the type it claims was improperly excluded.

First, Cordis' argument that AVE was "using [Dr. Palmaz's] ideas" (Tr. at 129:1-10) was not an allegation of "copying" – it was just another way of articulating that AVE infringes the Palmaz '762 patent. "Copying," as a secondary consideration of nonobviousness, typically refers to a more specific showing that the infringer designed its product based on the patentee's product or patent. See, e.g., Akamai Techs., Inc. v. Cable & Wireless Internet Servs., Inc., 344 F.3d 1186, 1196-97 (Fed. Cir. 2003) ("copying" shown by evidence that infringer "expended significant effort to determine how [the patentee's] products worked" and "ultimately

decided to switch" to the patentee's system). Cordis did not allege that AVE based its design on the asserted claims or on Cordis' products, and therefore did not allege "copying." The Court's decision to continue to exclude evidence that might have been relevant to rebutting an allegation of copying, such as AVE's own patents, was therefore correct.

Second, Cordis' arguments that Dr. Palmaz's ideas "created an industry" were not an effort to use AVE's success to prove nonobviousness, and did not open the door to evidence showing a lack of nexus between AVE's stents and the asserted claims. Stratoflex v. Aeroquip Corp., 713 F.2d 1530 (Fed. Cir. 1983), the single case AVE cites, is not on point. In Stratoflex, the "entire industry" consisted of two licensees, and the court considered whether a nexus was shown between their licenses and the asserted claims. Id. at 1539. The only testimony by Cordis witnesses relating to "commercial success" was testimony that Cordis' own stents have had billions of dollars of sales. (See, e.g., Tr. at 442:23-443:21; Tr. at 456:6-12; Tr. at 457:9-458:5.) Cordis did not rely on the commercial success of AVE's stents.

Furthermore, it is disingenuous for AVE to argue that it was precluded from offering evidence showing that AVE's success was due to features not covered by the asserted patent claims. As the record shows, AVE's witness Mr. Allen and Dr. Wagoner both testified at length that AVE's tapered crowns were a "critical design feature" with clinical significance. (E.g., Tr. 1073:1-2 (Mr. Allen also testifying that "the reason" AVE was a "strong competitor" was "because of [its] tapered crowns"); see also supra Section II(B)(1) (quoting additional testimony)).

Moreover, Mr. Allen testified that the rings forming AVE stents are a "fundamental ***proprietary*** module" (Tr. at 1002:11-13 (emphasis added)) built through an "arduous," "expensive," and "complicated" process (Tr. at 1006:23-2) that only AVE uses (Tr. at

1012:22-24), and without which AVE's stents would not "end up with these nice rounded tapered crowns" and would not "perform the same way" (Tr. at 1016:1-8). Indeed, despite the Court's repeated rulings excluding testimony concerning AVE's patents, Mr. Allen ended his testimony by discussing those patents (Tr. 1065:22-1066:4 (emphasis added)):

> Q. And I think you talked a little bit about patents and so on. How early are some of the patents that Medtronic AVE has?
>
> A. They're ***back to the, you know, late '80s, early '90s, the same time frame that we're talking about before there were any stents on the market, Medtronic had patents in stents***.

Thus, even without Cordis "opening the door" to rebuttal evidence about the nexus between secondary considerations and the asserted claims, AVE introduced substantial evidence of the type it claims was excluded. Furthermore, the Court made clear that Cordis was not relying on the commercial success of AVE's stents by instructing the jury to consider "[c]ommercial success of ***Cordis's*** products covered by the patents in suit" as an indication of nonobviousness. (D.I. 1357 (Jury Charge) at 37.) There was no error by the Court with respect to the exclusion of AVE's evidence, and given the amount of evidence AVE offered despite the Court's ruling, there was also no prejudice to AVE.

C. Cordis' Counsel Did Not Make Improper Remarks or Arguments Warranting a New Trial

AVE additionally accuses Cordis' counsel of "litter[ing]" their "trial presentation…with irrelevant, inflammatory, and extraneous arguments" (AVE Br. at 17) that were based on facts not in evidence (AVE Br. at 20, 21), but the trial record shows that Cordis' presentation consisted of proper comments based entirely on facts that were in evidence. As one might expect, Cordis' counsel pointed the jury to facts that were favorable to Cordis and unfavorable to AVE, but never made a remark that was "prejudicial in the sense of affecting a substantial right" of AVE's. See Stambler, 2003 WL 22749855, at *7 (Ex. B) (citing Fineman v.

Armstrong World Indus., 980 F.2d 171, 206-07 (3d Cir. 1992) and holding that counsel's remarks must be considered in the context of the entire record).

First, AVE accuses Cordis of violating the Court's *in limine* ruling precluding Cordis "from offering evidence, argument, or testimony as to whether any witness thought of the apparatus claimed in the Cordis patents" (D.I. 1398 at 12) when it offered evidence that Dr. Palmaz and Dr. Gianturco, two pioneers in the stent field, pursued different solutions to the problem solved by the '984 invention. (AVE Br. at 17-19.) However, as the Court noted during a sidebar, AVE's motion was explicitly directed at precluding Cordis' counsel from asking AVE's expert Dr. Van Breda whether she had thought of the invention, as happened at the 2000 trial. (Tr. 1510:10-15.) Cordis did not violate the "letter" or the "spirit" of the Court's ruling.

Moreover, the Court properly allowed in Cordis' evidence that Dr. Gianturco and Dr. Palmaz pursued different solutions to the flexibility problem solved by the '984 invention. AVE complains that Cordis should only have offered evidence as to what a "hypothetical person" would have thought, not what these two pioneers thought. (AVE Br. at 18.) But the Federal Circuit has found individual experts' personal "disbelief" that a solution would "adequately solve the problem" to be "highly probative…of nonobviousness." Envtl. Designs, Ltd. v. Union Oil Co., 713 F.2d 693, 697 (Fed. Cir. 1983). The personal disbelief of Dr. Palmaz and Dr. Gianturco, leading contemporary experts in the field of stenting, is no less relevant. Furthermore, AVE relied on a reference by Dr. Gianturco that described a straight connector as prior art. The evidence that Dr. Gianturco pursued a different solution despite having authored that reference went to show that "a person of ordinary skill" (here, Dr. Gianturco) would "upon reading the reference … be led in a direction divergent from the path that was taken by" the

inventor of the '984 patent. In re Gurley, 27 F.3d 551, 553 (Fed. Cir. 1994) (describing when a reference "teaches away"). The Court correctly admitted this evidence and argument.

Second, AVE identifies a laundry list of snippets of arguments that it claims warrant a new trial because they were "based upon purported facts not in evidence" and were designed to "elicit a favorable verdict based upon emotion, not reason." (AVE Br. at 20-23.) But the record shows that all of these arguments were based on facts in evidence:

- Cordis' counsel's argument that AVE "wants to avoid paying for the right to use Dr. Palmaz's work," unlike other companies, was based on undisputed testimony by Cordis' witness Bob Croce that AVE did not ask Cordis' permission to use the Palmaz and Schatz inventions (Tr. at 458:11-459:3), that AVE never paid Cordis for using those inventions (id.), and that other companies – including Abbott and Johnson & Johnson itself – did pay for the right to use those inventions (Tr. 432:5 – 433:3, 495:4-19).
- Cordis' argument that the jury "[could] conclude from the evidence" that Cordis acquired the "nutty" Hammerslag patent in order to challenge the Palmaz patent was supported by the license from Hammerslag to Cordis (DX 2599, admitted at Tr. 907:9-12), by Dr. Buller's testimony that Hammerslag's invention was based on "a completely wrong concept" for treating restenosis (Tr. 672:4-9), and by Dr. Heuser's admissions that "Mr. Hammerslag's idea was never used by anyone" (Tr. 1599:20-23) and that there is "no material…known to man" with properties necessary to make Hammerslag's invention (Tr. 1597:20-22).
- Cordis' argument that the jury should not give weight to Dr. Ersek's award from World Medical Inc. was supported by Dr. Ersek's own testimony that World Medical

was a medical device company and that after receiving the award he "came to understand" that World Medical "was interested in attacking the validity of the Palmaz patents." (Tr. at 1341:17-1343:3.)

A new trial cannot be granted because some facts in the record were unfavorable to AVE. Cordis' arguments based on these facts were perfectly proper and certainly do not "rise[] to the level of misconduct, affecting a substantial right in the context of the entire trial record." Genzyme Corp., 315 F. Supp. 2d at 587 (rejecting argument that counsel's remarks that the case "was about 'corporate wrongdoing' and the 'dark side' of corporate America," among others, warranted a new trial); see also Intel Corp. v. Broadcom Corp., 2003 WL 360256, at *26-27 (D. Del. Feb. 13, 2003) (attached hereto as Ex. C) (denying new trial requested on grounds that counsel made overly dramatic and emotional arguments where counsel did not ask the jury "to ignore [the] facts out of sympathy").

D. The Jury's Verdict Was Supported By Substantial Evidence

Finally, AVE argues that a new trial is warranted because "the verdict is contrary to the great weight of the evidence" (AVE Br. at 29), but the scant attention AVE devotes to this argument belies AVE's claim.

As shown above, Cordis offered more than substantial evidence that AVE's stents infringe the "substantially uniform thickness" limitation of the asserted claims. (See supra Section IA). Furthermore, the admissions of AVE's sole infringement expert, Dr. Wagoner, fatally undermined his testimony to the contrary. Dr. Wagoner agreed that for 98 percent of the stent – all of the struts and more than half of the crowns – he would measure the wall thickness as the "maximum thickness of the cross-section" of the stent, the very dimension that Cordis argued was the wall thickness of the stent. (Tr. at 1146:23 – 1147:5.) He also agreed that that 98 percent of the stent had the same "rounded edges" as the remaining 2 percent of the stent. (Id.)

The jury could reasonably have questioned Dr. Wagoner's testimony that those rounded edges, which are present everywhere, cause 2 percent of the stent to have a different thickness, and could reasonably have found more credible Cordis' evidence that one of ordinary skill in the art would measure the thickness of the entire stent wall the same way.

Cordis also offered overwhelming evidence of nonobviousness, including evidence that one of ordinary skill in the art would not have the motivation to combine the prior art references at issue to create the '762 invention and evidence that the prior art did not disclose the '984 invention.

Cordis' expert Dr. Buller analyzed the prior art Ersek patent at length (Tr. at 741:6-761:22) and testified in conclusion that because Ersek 'has nothing to do with the nonsurgical techniques that Palmaz is talking about, it is of no use" to a "scientist trying to improve upon angioplasty." (Tr. at 761:11-22; see also Tr. at 964:4-15 (Dr. Buller testifying that Ersek invention is the "antithesis" of the '762 invention because patent teaches its use as a replacement for sutures during conventional open-heart surgery).) AVE's expert cardiologist, Dr. Heuser, agreed that there are vast differences between the Ersek and Palmaz inventions, and even corrected Cordis' counsel when he forgot to mention one of those differences (Tr. at 1604:14-1605:6):

> Q. …[A]ll you had to do to turn Ersek into Palmaz was take away its staple-like attributes by flattening it, take away its expander gun, take away cutting open the body cavity and replace that by a flattened device that you insert in the femoral artery and deliver transluminally through the body's passageways to the coronary arteries of the beating heart, that's what you do; right?
>
> A. Yes. And you have to make it a smaller size.
>
> Q. I'm sorry, you also have to make the smaller size because if you took that one-inch Ersek, it would be a pretty ugly thing to insert into a body passageway; right?
>
> A. Yes.

See also Tr. at 779:10-794:21 (Dr. Buller explaining why AVE's two additional prior art references, the Hammerslag patent and Palmaz abstract, did not render the asserted claims obvious).

Cordis also offered substantial evidence to rebut AVE's contention that the '984 invention was obvious, showing that the prior art relied upon by AVE did not teach the '984 patent's solution to the problem of longitudinal flexibility. (See Tr. at 823:20-833:9 (Dr. Buller); see also, e.g., Tr. 819:12-823:19 (Dr. Buller testifying that the '984 invention was not obvious because one of ordinary skill would not have been motivated to connect short stents with a rigid connector to solve the problem of longitudinal flexibility); Tr. 801:20-814:15 (Dr. Buller testifying that the secondary considerations support finding the '984 claims nonobvious).)

Furthermore, Cordis offered evidence of each of the secondary considerations of nonobviousness:

- Long felt need and failure of others to solve the problem solved by the invention: Cordis showed that balloon angioplasty had significant drawbacks and that before Dr. Palmaz's invention, no one had been able to improve upon balloon angioplasty. (E.g., Tr. 268:14-276:13 (testimony of Cordis expert Dr. Fischell));
- Expressions of disbelief or skepticism: Cordis offered evidence that in the 1970's and 1980's, prior to Dr. Palmaz's invention, medical scientists were "very, very concerned about the concept of leaving prosthetic material, in particular, metal behind in coronary arteries" (Tr. 636:4-637:3 (Dr. Buller)), and that scientists were unconvinced that stenting could improve on angioplasty – including a 1991 New England Journal of Medicine editorial stating that the development of stents was "probably futile." (Tr. 652:12-654:20 and PX 185; see also, e.g., Tr. 330:10-332:1

and PX 3658 (Dr. Palmaz testifying that medical device companies he contacted in the early 1980s saw a "disadvantage" in leaving a prosthetic material in an artery); Tr. 1406:18-1414:9 (AVE expert Dr. Piehler testifying concerning the failure of the Shiley heart valve and the resulting concern in the medical community about putting an implant in the coronary arteries); Tr. 1587:9-16 (Dr. Heuser agreeing there were doubts about whether Dr. Palmaz's invention would work); and PX 854);

- Unexpected results: Cordis showed that despite the doubts of medical researchers, and unlike other metal implants, the Palmaz-Schatz stent embodying the '762 and '984 inventions was the first treatment proved to have clinical results superior to angioplasty. (E.g., Tr. at 645:22-647:12 and PX 186 (Dr. Buller testifying that 1991 New York Times article reported "pretty awful" results for self-expanding stents); Tr. at 1568:7-1569:14 and 1576:6-1577:7 (Dr. Heuser agreeing that there were "some doubts" about the patented invention before the landmark STRESS and BENESTENT trials, which proved for the first time that a treatment – the Palmaz-Schatz stent – "was superior to angioplasty in terms of patient outcomes"));
- Praise of the invention by the infringer or others in the field: Cordis offered numerous articles giving acclaim to Dr. Palmaz, and numerous awards from professional organizations to Dr. Palmaz in recognition of the merits of the '762 invention. (E.g., Tr. 362:14-367:16 and PX 7611, 7618, and 7607 (Dr. Palmaz testifying about his awards for the invention described in the patents in suit, and that the Smithsonian asked him to donate his early stent artifacts); Tr. 735:5-740:16 and PX 225, PX 3810, PX 277 (Cordis' expert Dr. Buller describing acclaim for Dr. Palmaz as inventor of balloon-expandable stent covered by asserted claims));

- Commercial success of Cordis' products covered by the patents in suit: Cordis showed that its stents embodying the '762 and '984 patents' inventions have had hundreds of millions of dollars of sales due to the features of the asserted claims. (E.g., Tr. at 442:23-443:21 (Palmaz-Schatz stent had $800 million in sales in first 2.5 years on market); Tr. at 456:6-12 (Cordis' Bx Velocity and Cypher stents have over $4.5 billion in sales); Tr. at 457:9-458:5 (Palmaz stent has had $350 million in sales); Tr. at 797:1-799:13, 801:20-803:21, 838:16-839:10 (Dr. Buller testifying that Cordis' products are covered by the asserted claims and that their success is attributable to the patented inventions)); and
- Licenses: Cordis offered evidence that a major competitor licensed the '762 patent for a "substantial" royalty. (Tr. at 459:4-19.)

Thus, the record shows that far from relying "extensively on irrelevant arguments" (AVE Br. at 30), Cordis offered overwhelming evidence, largely undisputed by AVE's own experts, that the asserted claims were not obvious. No "miscarriage of justice would result" if this jury's verdict is allowed to stand. See Eaton Corp. v. Parker-Hannifin Corp., 292 F. Supp. 2d 555, 578-579 (D. Del. 2003) (denying new trial for nonobviousness where "both sides presented evidence to support their argument"). To the contrary, justice is best served in this case by upholding this second jury verdict in Cordis' favor. AVE's motion for a new trial should be denied.

CONCLUSION

For the reasons set forth above, this Court should deny AVE's motion for judgment as a matter of law that the accused products do not infringe claims 23, 51 and 54 of the

'762 patent and claims 1 and 3 of the '984 patent. Furthermore, this Court should also deny AVE's motion for a new trial.

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156912.1

CERTIFICATE OF SERVICE

I hereby certify that on the 5th day of May, 2005, the attached **CORDIS'**

COMBINED ANSWERING BRIEF IN OPPOSITION TO AVE'S MOTION FOR JMOL ON INFRINGEMENT OF THE PALMAZ '762 AND SCHATZ '984 PATENTS AND ITS MOTION FOR A NEW TRIAL was served upon the following counsel of record in the manner indicated:

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